

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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SANOFI-SYNTHELABO;	:
SANOFI-SYNTHELABO, INC.; and	:
BRISTOL-MYERS SQUIBB SANOFI	:
PHARMACEUTICALS	:
HOLDING PARTNERSHIP,	:
	<u>OPINION &amp; ORDER</u>
Plaintiffs,	:
	:
-against-	:
	:
APOTEX INC.; and APOTEX CORP.,	:
	:
Defendants.	:
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SIDNEY H. STEIN, U.S. District Judge.

Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”) move pursuant to Fed. R. Civ. P. 15(a) and 15(d) to amend and supplement their Third Amended Answer, resulting in a Fourth Amended Answer, in this action.<sup>1</sup> The motion is denied to the extent Apotex seeks to add the defense of unclean hands and the counterclaim for breach of contract on the grounds that adding those claims would unduly prejudice plaintiffs. The motion is granted, however, insofar as it seeks to amend and supplement the answer with additional antitrust counterclaims. In addition, those antitrust counterclaims are severed pursuant to Fed. R. Civ. P. 21 and stayed pending resolution of the issues scheduled for trial commencing January 22, 2007.

## I. Background

On March 21, 2002, plaintiffs Sanofi-Synthelabo, Sanofi-Synthelabo, Inc., and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (collectively, “Sanofi”) filed this patent infringement suit against Apotex. The history of this litigation is recounted in the Opinion

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<sup>1</sup> The standard to be employed by this Court is identical whether the motion is one to amend or to supplement. See Hassan v. Slater, 41 F. Supp. 2d 343, 353 (E.D.N.Y. 1999).

dated August 31, 2006 granting Sanofi's motion for a preliminary injunction, and familiarity with that opinion is assumed. See Sanofi-Syntholabo v. Apotex Inc., No. 02 Civ. 2255, 2006 U.S. Dist. LEXIS 65127, at \*5-16 (S.D.N.Y. Aug. 31, 2006).

On April 12, 2005, the Court denied a motion by Apotex to amend its Third Amended Answer. Apotex now moves a second time to amend its Third Amended Answer. Specifically, Apotex seeks to assert the equitable defense of unclean hands (Defendant's Proposed Answer ("Prop. Ans.") at 6-9, ¶ 8) and counterclaims for breach of contract relating to the March 17, 2006 settlement agreement between the parties (Prop. Ans. ¶¶ 97-109) and additional antitrust violations (Prop. Ans. ¶¶ 70-97). In addition, Apotex seeks a declaration that any infringement damages awarded to Sanofi be subject to the cap on damages set forth in the May 25, 2006 settlement agreement.<sup>2</sup>

## **II. Legal Standard**

The decision to grant or deny a motion to amend a pleading rests within "the sound discretion" of the district court. Krumme v. Westpoint Stevens Inc., 143 F.3d 71, 88 (2d Cir. 1998). While leave to amend should be given freely, the district court "plainly has discretion to deny leave to amend 'where the motion is made after inordinate delay, no satisfactory explanation is made for the delay, and the amendment would prejudice the defendant.'"

MacDraw, Inc. v. The CIT Group Equip. Fin., Inc., 157 F.3d 956, 962 (2d Cir. 1998) (quoting Cresswell v. Sullivan & Cromwell, 922 F.2d 60, 72 (2d Cir. 1990)). Additional factors that a court may consider include repeated failure to cure deficiencies by previous amendments or

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<sup>2</sup> Sanofi has not specifically opposed the amendment seeking a declaration that infringement damages have been capped, and the Court permits that amendment.

In its motion, Apotex also asserted the defense of inequitable conduct regarding Sanofi's alleged failure to disclose Canadian patent 1,194,875 to the U.S. Patent and Trademark Office (the "PTO"). Apotex has withdrawn that portion of the motion on the basis that those allegations "were included by error." (Def. Reply Mem. dated Oct. 23, 2006 at 1 n.1.)

futility of the proposed amendments. Foman v Davis, 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed. 2d 222 (1962). The court also has discretion to deny leave to amend “where the belated motion would unduly delay the course of proceedings by, for example, introducing new issues for discovery.” Grace v. Rosenstock, 228 F.3d 40, 42 (2d Cir. 2000) (citing Ansam Associates v. Cola Petroleum, Ltd., 760 F.2d 442, 446 (2d Cir. 1985)). As to prejudice, the Court considers factors including whether the new claim would “require the opponent to expend significant additional resources to conduct discovery and prepare for trial” or would “significantly delay the resolution of the dispute.” Block v. First Blood Associates, 988 F.2d 344, 350 (2d Cir. 1993). See also Krumme, 143 F.3d at 88 (quoting H.L. Hayden Co. v. Siemens Medical Systems, 112 F.R.D. 417, 419 (S.D.N.Y. 1986) (“One of the most important considerations … is the degree to which [allowing amendment] would delay the final disposition of the action.”)).

### **III. Discussion**

#### **A. “Unclean Hands” Defense and Counterclaim for Breach of Contract**

Sanofi asserts that Apotex’s proposed unclean hands defense and counterclaim for breach of contract (together, the “Settlement Allegations”) “relate exclusively to the settlement agreements executed by the parties in 2006 and the ensuing review of those agreements by government regulators.” (Pl. Mem. in Opp. dated Oct. 13, 2006 (“Pl. Mem.”) at 6.) Sanofi further contends that “the utter lack of any relationship” between the Settlement Allegations and the issues ready for trial on January 22, 2007—namely, whether U.S. Patent No. 4,847,265 (the “‘265 patent”) is valid and enforceable—requires the Court to deny Apotex’s motion as it relates to those proposed amendments. Apotex replies that Sanofi’s conduct during settlement negotiations relates directly to the validity and enforceability of the ‘265 patent and should therefore be included in the January trial. Specifically, Apotex alleges that Sanofi engaged in

misconduct during the settlement process in order to “perpetrate a fraud on government regulators.” (Def. Reply Mem. at 5.)

Apotex cites Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 65 S. Ct. 993, 89 L.Ed. 1381 (1945), to support its contention that “the doctrine of ‘unclean hands’ bars the enforcement of a patent by a party who has abused the settlement process as a way to shield the patent from judicial scrutiny.” (Def. Reply Mem. at 5.) However, as this Court has written previously, Precision Instrument stands for the proposition that unclean hands may bar equitable relief when parties “committed perjury before the PTO, or litigation misconduct or fraud on the court,” but the decision does not support denial of equitable relief on the basis of “alleged wrongdoing during the course of settlement negotiations.” Sanofi-Syntholabo, 2006 U.S. Dist. LEXIS 65127, at \*88. See, e.g., Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 244-46, 54 S. Ct. 146, 78 L.Ed. 293 (1933) (fraud on the court); Aptix Corp. v. Quickturn Design Sys., Inc., 269 F.3d 1369, 1374 (Fed. Cir. 2001) (litigation misconduct); see also Republic Molding Corp. v. B.W. Photo Utilities, 319 F.2d 347, 351 (9th Cir. 1963). The wrongdoing during the course of settlement negotiations alleged here is unrelated to the procurement of the patent itself and will not be part of the January trial on the validity and enforceability of the patent.

Defendants’ reliance on Morton Salt v. G.S. Suppiger, 314 U.S. 488, 62 S. Ct. 402, 86 L.Ed. 363 (1942) is also unavailing. In Morton Salt, the patentee used its patent to restrain competition in related articles on which it did not hold patent rights. Id. at 491. Because the patentee’s infringement suit was deemed an effort to further its unlawful monopoly over an unpatented article, the Supreme Court determined that the district court had rightly dismissed the complaint for patent misuse “for want of equity.” Id. at 494. Morton Salt, however, is

inapposite to Apotex's position. First, the continued validity of Morton Salt is suspect in light of the Supreme Court's recent opinion in Illinois Tool Works Inc. v. Independent Ink, Inc., \_\_\_ U.S. \_\_\_, 126 S. Ct. 1281, 1288 164 L.Ed. 2d 26 (2006). Second, the facts of Morton Salt, which deal specifically with the misuse of a patent to restrain trade beyond the scope of the patent, differ substantially from allegations of misconduct arising out of the negotiation of an agreement between patentee and potential licensee.

The Court has previously written in this litigation that “[t]he conduct of the parties during settlement negotiations does not affect the validity of the patent or the veracity of submissions to this Court.” Sanofi-Syntholabo, 2006 U.S. Dist. LEXIS 65127, at \*89. That statement holds true today. Exclusion of the unclean hands defense that Apotex seeks to introduce into this action does not prevent Apotex from arguing at trial that Sanofi engaged in inequitable conduct during the prosecution of its application for the ‘265 patent before the PTO, to the extent Apotex has already alleged that inequitable conduct. In contrast, whether Sanofi attempted to conceal inequitable conduct dating to its application to the PTO in the late 1980s by entering into settlement negotiations with Apotex in 2006 is an unnecessary and inappropriate diversion from the question presented for trial: whether the ‘265 patent is valid and enforceable.

Indeed, the lack of connection between the Settlement Allegations on the one hand and the issue of the validity and enforceability of the ‘265 patent on the other suggests why inclusion of the Settlement Allegations at this stage would unduly prejudice Sanofi. The Settlement Allegations would of necessity require the reopening of discovery since the negotiations surrounding the settlements were not part of the prior discovery proceedings. Apotex asserts that additional discovery would be feasible between now and the trial date—a period of less than three months—but the history of time-consuming discovery in these litigations demonstrates that

permitting discovery on new issues at this late date would risk further delay and expense in this four year-old litigation.<sup>3</sup> Under these circumstances, allowing the proposed amendments would prejudice Sanofi. See, e.g., Zubulake v. UBS Warburg LLC, UBS, 231 F.R.D. 159, 162-63 (S.D.N.Y. 2005); Cartier, Inc. v. Four Star Jewelry Creations, Inc., No. 01 Civ. 11295, U.S. Dist. LEXIS 989, at \*9-11 (S.D.N.Y. Jan. 28, 2004). Accordingly, Apotex's motion is denied to the extent it seeks to add the Settlement Allegations to this litigation.

#### B. Allegations of Additional Antitrust Violations

Apotex also seeks to include additional antitrust counterclaims (the "Antitrust Allegations"). Specifically, Apotex seeks to allege that Sanofi entered into an agreement with a third party, Prasco Laboratories or Prasco LLC, to market an authorized generic with the goal of excluding Apotex from the market for clopidogrel bisulfate. Like the Settlement Allegations, the Antitrust Allegations relate to agreements and conduct that are distinct from the narrow question of patent validity and enforceability. Furthermore, the Antitrust Allegations will also require additional discovery, particularly given the alleged involvement of third parties. Nonetheless, as both parties acknowledge, antitrust counterclaims have already been asserted in this litigation, and have been severed pursuant to Fed. R. Civ. P. 21 and stayed pending the outcome of the January trial. See Joint Pre-Trial Order dated July 11, 2005, at 5.

In exercising its discretion to sever claims, the Court considers "(1) whether the claims arise out of the same transaction or occurrence; (2) whether the claims present some common questions of law or fact; (3) whether settlement of the claims or judicial economy would be

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<sup>3</sup> In addition, if the Settlement Allegations are added to this litigation, the result may be that the entire action would need to be stayed, since the events surrounding the settlement negotiations are under investigation by the Department of Justice, see Pl. Mem. at 7-8, which has the ability to seek a stay of these proceedings if it believes they would compromise an ongoing criminal investigation. See, e.g., SEC v. Chestman, 861 F.2d 49, 50 (2d Cir. 1988); SEC v. Downe, No. 92 Civ 4092, 1993 WL 22126, at \*11 (S.D.N.Y. Jan. 26, 1993). Although the possibility of a stay is speculative at this point, it weighs against adding the Settlement Allegations to this litigation.

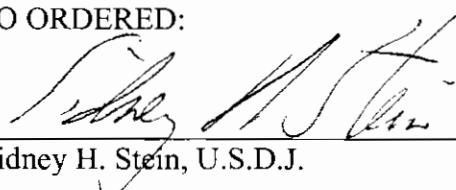
facilitated; (4) whether prejudice would be avoided if severance were granted; and (5) whether different witnesses and documentary proof are required for the separate claims.” Preferred Med. Imaging, P.C. v. Allstate Ins. Co., 303 F. Supp. 2d 476, 477 (S.D.N.Y. 2004). The Antitrust Allegations arise out of recent commercial activity that is distinct from the underlying patent dispute. In addition, the Antitrust Allegations principally concern questions of antitrust law and contract law, not patent law. Judicial efficiency would not be served by the simultaneous trial of the Antitrust Allegations and the patent dispute, and neither party would be prejudiced by the severance of the Antitrust Allegations from this action. The motion is therefore granted to the extent it seeks to supplement the answer with the Antitrust Allegations, and those allegations are severed pursuant to Fed. R. Civ. P. 21 and stayed pending the conclusion of the trial commencing on January 22, 2007.

#### **IV. Conclusion**

For the reasons set forth above, the motion by Apotex for leave to amend the answer is denied insofar as it seeks to add the equitable defense of unclean hands and the counterclaim for breach of contract. The Court grants the motion, however, insofar as it seeks to add additional antitrust counterclaims, but those claims are severed pursuant to Fed. R. Civ. P. 21 and stayed pending resolution of the issues scheduled for trial on January 22, 2007. Apotex is directed to file a Fourth Amended Answer pursuant to this Opinion and Order within 20 days.

Dated: New York, New York  
November 2, 2006

SO ORDERED:



Sidney H. Stein, U.S.D.J.